K010109

FEB 2 8 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

FLUOROPERM® 151-OK AND PARAGON HDS 100-OK (paflufocon D)

RGP CONTACT LENSES FOR ORTHOKERATOLOGY

Submitter

Company Name:	**Paragon Vision Sciences**
Address:	**947 East Impala Ave., Mesa, AZ 85204**
Phone:	**480-892-7602**
Fax:	**480-892-3226**
Registration:	Owner Operator # **9024618**

Manufacturer Information

Company Name:	**Paragon Vision Sciences**
Address:	**947 East Impala Ave. Mesa AZ 85204**
Phone:	**480-892-7602**
Fax:	**480-892-3226**
Registration:	Site Registration **#2020433**

Official Correspondent

Name:	**William E. Meyers**
Company Name:	**Paragon Vision Sciences**
Address:	**947 East Impala Ave. Mesa AZ 85204**
Phone:	**480-507-7606**
Fax:	**480-892-3226**

Reason for 510(k) Submission: **New Indication**

Device Identification

Trade Name:	**FluoroPerm® 151-OK, Paragon HDS 100-OK**
Common Name:	**Fluorosilicone acrylate rigid gas permeable contact lens material**
Classification Name:	**Rigid gas permeable (hydrophobic) contact lens; Class II, for daily wear**
Reference:	**21 CFR 886.5916, Ophthalmic: 86 HQD**
Material Covered By PMA:	**paflufocon D; approved, PMA P87024-S36**

Device Description

The FluoroPerm® 151-OK and Paragon HDS 100-OK (orthokeratology) contact lenses are rigid gas permeable (RGP) contact lenses in a reverse geometry design. The lens material, paflufocon D, is a fluorosilicone acrylate polymer which may contain one or more of the following color additives; D&C Green No. 6 and Perox Yellow No. 9 which provide a handling aid in locating the lens. The paflufocon D material is a thermoset copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate, and methylmethacrylate.

The paflufocon D [FluoroPerm® 151-OK or Paragon HDS 100-OK (orthokeratology)] daily wear contact lenses produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye. If the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. The contact lens rests directly on the corneal tear layer and can influence the corneal shape. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A retainer lens must be used each day to maintain the corneal flattening, or the myopia will revert to the pre-treatment level.

Description of Safety and Efficacy

The safety and efficacy of the paflufocon D (FluoroPerm® 151-OK or Paragon HDS 100-OK) contact lens material was demonstrated in approved PMA P87024-S36. Also, the use of a rigid gas permeable contact lens in an orthokeratology fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters was cleared in 510(k) Premarket Notification No. K000224.

Indication for Use

The paflufocon D [FluoroPerm® 151-OK or Paragon HDS 100-OK (orthokeratology)] daily wear rigid gas permeable contact lenses are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lens may be disinfected using only a chemical disinfecting system.

Predicate Device And Substantial Equivalence

The FluoroPerm® 151-OK or Paragon HDS 100-OK (paflufocon D) RGP Contact Lens for Orthokeratology is substantially equivalent to the Paragon HDS-OK™ (paflufocon B) RGP Contact Lens for Orthokeratology, which was cleared in 510(k) Premarket Notification No. K000224.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

William E. Meyers, Ph.D.
Paragon Vision Sciences
947 East Impala Ave.
Mesa, AZ 85204

Re: K010109
Trade Name: Paragon HDS 100-OK (paflufocon D) Daily Wear Rigid Gas Permeable Contact Lens and FluoroPerm® 151-OK (paflufocon D) Daily Wear Rigid Gas Permeable Contact Lens for Orthokeratology
Regulatory Class: II
Product Code: MUW, HQD
Dated: January 11, 2001
Received: January 12, 2001

Dear Dr. Meyers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicte devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System

Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions.

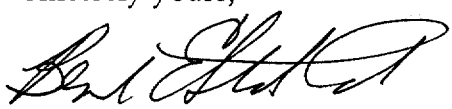
Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Bernard E. Statland, M.D.,Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010105

Indications For Use Statement

510(k) Number (unknown):

Device Name:

Paragon HDS 100-OK (paflufocon D) daily wear rigid gas permeable contact lens

Indications For Use:

The Paragon HDS 100-OK (paflufocon D) daily wear rigid gas permeable contact lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lens may only be disinfected using a chemical disinfecting system.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010105

Indications For Use Statement

510(k) Number (unknown):

Device Name:

FluoroPerm®151-OK (paflufocon D) daily wear rigid gas permeable contact lens

Indications For Use:

The FluoroPerm®151-OK (paflufocon D) daily wear rigid gas permeable contact lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lens may only be disinfected using a chemical disinfecting system.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010109